K093426

510(k) Summary
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11-Feb-10

FEB 22 2010

Pharma Systems AB
Rubanksgatan 9
S741 71 Knivsta Sweden

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Official Contact: Viljar Salumaa, Product Manager

Proprietary or Trade Name: Bact-Trap™ HEPA Midi

Common/Usual Name: Bacterial / Viral Filter

Classification Name: Filter, Bacterial, Breathing Circuit,
CAH – 21 CFR 868.5260

Predicate Devices: ARC Medical – FilterFlo™ HEPA – K063125
Air Safety – Model 6500/01 – K033008

Device Description
The Bact-Trap™ HEPA Midi filter incorporates standard 15 / 22 mm connectors with a gas sampling luer port. It utilizes an electrostatic media for the filtration function. The "HEPA" performance was tested in accordance to DOE 3020-97 and ASTM D2986 – 95a DOP at 30 lpm.

The filter functions by electrostatic capture.

Indications for Use
For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and / or expired gases is required. It is intended for patients with Tidal Volumes > 150 ml.

May be positioned at the machine end of the expiratory / inspiratory limb of the circuit, or at the patient end of the circuit.

Environment of Use

Home, Hospital, Sub-acute Institutions, Emergency services

General Technical Characteristics

Attribute	**Proposed devices**
Indications for use - To filter inspired and / or expired gases.	Yes
Intended for single patient use	Yes
Prescription	Yes
Intended population	> 150 ml tidal volume
Intended Environment of Use	Home, Hospital, sub-acute, Emergency services
Placement in various locations in circuit	Yes
Design	
Gas sampling port	Yes
Standard 15/22 mm connectors	Yes
Dead Space (ml)	46 ml for straight, 48 ml for angled
Resistance to flow	$\leq$ 3.1 cm H_2O @ 60 lpm
Bacterial filtration – BFE – Nelson Lab.	99.9999%
Viral filtration – VFE – Nelson Lab.	99.9999%
HEPA Filtration	>99.97%
Weight (gm)	32 gm
Materials	
Housing polystyrene	Yes
Filter media	Electrostatic
Performance Standards	
None under Section 514	Yes
ISO 5356-1 Conical 15/22	Yes
ISO 594-2 Luer Fittings	Yes
DOE 3020-97 and ASTM D2986 – 95a DOP	Yes

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed devices when compared to the predicate devices are safe and effective and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pharma Systems AB
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

FEB 22 2010

Re: K093426
Trade/Device Name: Bact-Trap™ HEPA Midi
Regulation Number: 21CFR 868.5260
Regulation Name: Breathing Circuit Bacterial
Regulatory Class: II
Product Code: CAH
Dated: February 11, 2010
Received: February 16, 2010

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number: **K093426** (To be assigned)

Device Name: Bact-Trap™ HEPA Midi

Indications for Use:

For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and / or expired gases is required. It is single patient use, disposable for patients with Tidal Volumes > 150 ml.

May be positioned at the machine end of the expiratory / inspiratory limb of the circuit, or at the patient end of the circuit.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheis

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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